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(54) Title: APPARATUS AND METHOD FOR TREATING FEMALE URINARY INCONTINENCE

(57) Abstract: The present invention provides a surgical implant and method for supporting the urethra, the implant comprising: comprising at least one fixing zone that can be fixed in the fibrofatty tissue of the retropubic space. In use the implant supports the urethra such that increased intra-abdominal pressure is transmitted to the sub urethral pressure space to promote occlusion of the urethra at periods of increased intra-abdominal pressure. The implant of the present invention has uses including treating urinary incontinence and uterovaginal prolapse.

1 **"Apparatus and Method for Treating Female Urinary**
2 **Incontinence"**

3

4 The present invention relates to an apparatus and
5 method for treating female urinary incontinence. In
6 particular, the invention provides a surgical
7 implant that passes under the urethra in use and
8 supports the urethra, the implant being anchored in
9 the retropubic space is provided.

10

11 Urinary incontinence affects a large number of women
12 and, consequently, various approaches have been
13 developed to treat female urinary incontinence.
14 Those skilled in the art will be familiar with
15 approaches ranging from pelvic floor exercises to
16 surgical techniques such as Burch colposuspension
17 and Stamey-type endoscopic procedures in which
18 sutures are placed so as to elevate the bladder
19 neck.

20

21 This invention is particularly directed to
22 improvement of a known procedure in which a sling is

1 positioned loosely under the urethra, commonly known
2 as TVT (tension free vaginal tape) and described,
3 for example, in International Patent Applications
4 No. WO97/13465 and WO96/06567. It is generally
5 understood that this treatment alleviates urinary
6 incontinence by occluding the mid-urethra (for
7 example at a time of raised abdominal pressure by
8 coughing or the like).

9
10 In order to provide a sling loosely under the
11 urethra using the apparatus and method of the prior
12 art, an incision is made in the anterior vaginal
13 wall and a first needle is passed through the
14 incision, past one side of the urethra, behind the
15 pubic bone, through the rectus sheath and out
16 through the lower anterior abdominal wall.
17 Likewise, a second needle is passed through the
18 incision, past the other side of the urethra, behind
19 the pubic bone, through the rectus sheath and out
20 through the lower abdominal wall. The needles are
21 separated from their respective insertion tools and
22 also from the mesh or tape such that only the tape
23 and its plastics sleeve are left in the body,
24 passing from a first exit point in the lower
25 abdominal wall, through the rectus sheath, behind
26 the pubic bone, under the urethra, back behind the
27 pubic bone, back through the rectus sheath and out
28 through a second exit point in the lower abdominal
29 wall.

30
31 The plastics sleeve is then removed from the tape
32 and the tape adjusted to a suitable tension..(such .

1 that the tape provides a sling that passes loosely
2 under the urethra, as described above) by
3 manoeuvring the free ends of the tape outside the
4 exit points in the lower abdominal wall whilst the
5 urethra is held using a rigid catheter inserted
6 therein. The tape is then cut such that it just
7 falls short of protruding from the exit points in
8 the lower abdominal wall. The exit points and the
9 incision in the upper vaginal wall are then closed
10 by sutures.

11
12 Whilst highly effective in treating urinary
13 incontinence, this procedure has a number of
14 problems. One such problem is that the needles used
15 for inserting the tape are comparatively large, with
16 the needles having, for example, a diameter of
17 around 5-6 mm and a length of around 200 mm. As
18 well as causing concern for patients viewing such
19 needles before or in some cases during the
20 procedure, the size of the needles can also lead to
21 a high vascular injury rate.

22
23 Similarly, the requirement that the needles exit the
24 lower abdominal wall is disadvantageous due to the
25 trauma to the patient in this area and the pain of
26 such abdominal wounds. A further disadvantage is
27 that, as the tape is required to extend from the
28 lower abdomen wall under the urethra and back
29 through the lower abdomen wall, the tape must
30 comprise a relatively large foreign body mass
31 (typically around 25 to 28 cm) to be retained within
32 the patient. This can lead to related inflammation,

1 infection translocation, erosion, fistula and such
2 like.

3

4 Similarly, the nature of the large needles and tape,
5 along with the tools required to insert these in the
6 body, lead to the procedure having a relatively high
7 cost.

8

9 Further details of the apparatus and methods of the
10 prior art are provided in the co-pending
11 International Patent Application No PCT/GB01/04554.

12

13 It would be advantageous if an implant such as a
14 sling could be inserted into the body such that it
15 is positioned loosely under the urethra without
16 requiring penetration of the abdominal wall or
17 rectus sheath. Most of the pain associated with
18 previous procedures to introduce an implant as
19 described above is due to the force required to
20 penetrate the tough structures of the abdominal wall
21 or rectus sheath, both of which are highly
22 innervated. The suitable location of an implant
23 such that it hangs loosely under the urethra without
24 requiring penetration of the lower abdomen or rectus
25 sheath would reduce the trauma experienced by the
26 patient. Further, a greater number of major blood
27 vessels are located in the retropubic space towards
28 the rectus sheath than toward the endopelvic fascia
29 and thus by suitably locating the implant, without
30 piercing the rectus sheath, damage to these blood
31 vessels would be minimised. This would reduce the
32 amount of bleeding experienced by the patient.

1

2 In addition, such location of an implant with a
3 reduced level of trauma may allow the procedure to
4 be performed under local anaesthetic in an out
5 patient or office setting.

6

7 Ideally an implant such as a sling used to treat
8 female urinary incontinence includes means to adjust
9 the position of the suburethral portion of the sling
10 such that this portion passes under the urethra and
11 is able to occlude the mid urethra at times of
12 raised abdominal pressure. In addition, the implant
13 should have minimal mass, when implanted in the
14 body, to reduce the likelihood of inflammation and
15 the like as discussed above.

16

17 According to the present invention there is provided
18 a surgical implant for supporting the urethra, the
19 implant including at least two fixing zones and a
20 supporting zone, the supporting zone being
21 interposed between the fixing zones and the fixing
22 zones each having at least one retaining means for
23 anchoring the fixing zones in the tissues of the
24 retropubic space, without penetrating the rectus
25 sheath such that in use the supporting zone passes
26 under the urethra.

27

28 Preferably the fixing zones are anchored in the
29 tissues of the retropubic space above the endopelvic
30 fascia.

31

1 The retropubic space above the endopelvic fascia
2 equates to the same pressure compartment as the
3 intra-abdominal pressure compartment.

4
5 Preferably the retaining means are moveable from an
6 inserting position to a retaining position.

7
8 Preferably the retaining means is at least one
9 projection which can project from the implant into
10 the tissues of the retropubic space in at least one
11 plane the projection being moveable from a collapsed
12 position to an extended position.

13
14 Where the retaining means are mechanical in nature
15 in an inserting position the mechanical means are
16 collapsed and in a retaining position the mechanical
17 retaining means are in an extended position.

18
19 Where the retaining means are chemical in nature,
20 for example glue in an inserting position the glue
21 is in a state which minimises its adhesion to the
22 surrounding tissue and in a retaining position the
23 glue is in a state which allows the glue to adhere
24 to the surrounding tissue. Thus in moving from a
25 inserting position to a retaining position the
26 presentation or the nature of the glue is changed to
27 cause the glue to adhere the implant to the
28 surrounding tissue.

29
30 The glue may be encapsulated (inserting position)
31 within a capsule such that the glue cannot interact
32 ~~with the tissue during placement of the implant.~~

1 When the implant is suitably located, the capsule of
2 glue may be burst (retaining position) to release
3 the glue and allow the implant to be fixed to the
4 surrounding tissue.

5
6 Alternatively the glue may be activated by some
7 means, for example heat, light, cold or ultrasound.
8 The implant can be moved into the retropubic tissue
9 without the glue adhering the implant to the
10 surrounding tissue (inserting position) then
11 following the activation of the glue or change in
12 state of the glue by some means, not limited to
13 heat, light, cold or ultrasound, the glue will
14 adhere the implant to the surrounding tissues
15 (retaining position).

16
17 It is preferable if the implant has minimal mass to
18 reduce the likelihood of inflammation or rejection
19 of the implant when it is located in the body.
20 Further, it is preferable that the implant comprises
21 as little material as allows support of the urethra
22 during periods of increased intra-abdominal pressure
23 to minimise the abrasion of the urethra and the
24 likelihood of adhesions forming at the urethra.

25
26 In addition, it is preferable if the fixing zone and
27 the supporting zone are integral with each other as
28 it allows easier manufacture of the implant. As the
29 distance from the supporting region under the
30 urethra to the fixing points in the retropubic space
31 are relatively short in comparison to the distances
32 between the supporting zone and the fixing zones

1 described in the implants of the prior art, the
2 overall size of the implant can be reduced.

3
4 The production of an implant from a portion of tape
5 material is preferable as it allows easier
6 manufacture than implants comprising multiple
7 portions comprising of different materials which
8 have to be fixed together, it minimises the risk of
9 failure of the implant due to the simplicity of the
10 implant and provides for easier packaging and
11 sterilisation of the implant.

12
13 It is preferable if at least one of the retaining
14 means of the implant is moveable from a collapsed
15 position to an extended position as it enables the
16 retaining means to actively move into tissue in at
17 least one layer of the tissue following suitable
18 location of the implant. The movement of the
19 retaining means from a collapsed position to an
20 extended position allows the means to move into and
21 be retained in tissue which was been undisturbed or
22 which has not been disrupted during placement of the
23 implant. The collapsed position of the implant can
24 be achieved by rolling up, folding, bending, or
25 enclosing the implant in a restrained position.

26
27 It is more preferable if the retaining means can be
28 moved from a collapsed position to an extended
29 position at two or more layers in the tissue as this
30 provides for gripping of the tissue by the implant
31 at multiple sites which may require increased force
32 ... to be used to dislodge ~~the fixing zones~~ of the

1 implant from the anchored positions in the
2 retropubic space.

3

4 The fixing zone of the implant must be anchored in
5 the tissues of the retropubic space with adequate
6 tensile strength to counter dislodging by coughing
7 until suitable integration of tissue occurs.

8 At least two forces are exerted on the tape which
9 extends under the urethra. A first force is the
10 force exerted by the urethra during increased intra-
11 abdominal pressure. The tape has to be secured in
12 the retropubic space such that it is capable of
13 supporting the urethra and occluding the urethra at
14 periods of increased intra-abdominal pressure, to
15 minimise incontinence.

16

17 A second force is the force exerted on the tape
18 during periods of increased intra-abdominal pressure
19 which acts in a direction opposite to the direction
20 in which the fixing means are inserted into the
21 retropubic space. This force can be considered to
22 be a force of dislodgement.

23

24 Preferably the implant is anchored in the tissues of
25 the retropubic space such that the implant can
26 resist forces of dislodgement created during periods
27 of increased intra-abdominal pressure.

28

29 Coughing and other causes of increased abdominal
30 pressure typically cause increased pressures of
31 around 200-400 cm water. This has been determined

1 by the Applicant to be equivalent to around a force
2 of 3.75 N through each tape arm.

3

4 Preferably the implant is anchored in the tissues of
5 the retropubic space such that the implant can
6 resist forces of dislodgement created during periods
7 of increased intra-abdominal pressure.of up to 3N.

8

9 More preferably the implant is anchored in the
10 tissues of the retropubic space such that the
11 implant can resist forces of dislodgement of up to
12 5N.

13

14 More preferably the implant is anchored in the
15 tissues of the retropubic space such that it can
16 resist forces of dislodgement of up to 10N.

17

18 Preferably each fixing zone comprises a plurality of
19 retaining means.

20

21 Preferably the fixing zones are tapered

22

23 Preferably the retaining means comprise a plurality
24 of projections extending laterally from the
25 longitudinal axis of the implant.

26

27 More preferably the projections extend from the
28 longitudinal axis of the implant such that they
29 point away from the bladder when the implant is
30 positioned such that the supporting zone passes
31 under the urethra.

1 Preferably the projections are curved such that they
2 point away from bladder when the implant is
3 positioned such that the supporting zone passes
4 under the urethra.

5

6 Preferably the implant is curved such that the
7 longitudinal edges of the fixing zone of the implant
8 and thus the retaining means in use are directed
9 away from the bladder.

10

11 Curvature of the longitudinal edges of the fixing
12 zone such that they are directed away from the
13 bladder minimises medial presentation of the
14 retaining means such as projections to the bladder
15 minimising erosion of the bladder.

16

17 Preferably the fixing zone comprises the shape of a
18 serrated arrowhead wherein the base portion of the
19 arrowhead is conjoined to the supporting zone.

20

21 The serrated arrowhead can be provided by cutting a
22 flat tape such that the serration's of the arrowhead
23 exist in two dimensions only.

24

25 Preferably the fixing zone has a pointed end at a
26 first end, a base portion at a second end, wherein
27 the longitudinal edges extend between the pointed
28 end and the base and the longitudinal edges are
29 notched to provide a row of projections extending
30 outward from the longitudinal edges.

31

1 In other words the fixing zone has a pointed tip at
2 a first end and a base portion at a second end, the
3 first end being the end of the fixing zone furthest
4 from the supporting zone the base portion being
5 conjoined to the supporting zone. The longitudinal
6 edges of the fixing zone extending from the pointed
7 tip to the base wherein the longitudinal edges are
8 notched to form a row of tooth like projections
9 extending from the longitudinal edge.

10

11 Alternatively the retaining means is glue.

12

13 Preferably the glue is cyanoacrylate glue.

14

15 More preferably the glue is held in a releasable
16 container. The glue containing releasable container
17 may prevent the glue interacting with surrounding
18 tissues until an appropriate point in the surgical
19 procedure. At this point the surgeon may use means,
20 for example a point on the introducing tool to
21 release the glue from the container, for example by
22 puncturing the container and enabling the glue to
23 adhere the implant to the surrounding tissue.

24

25 Preferably the implant is comprised of resilient
26 material such that if the implant is not restrained
27 it adopts the original shape defined during
28 production of the implant.

29

30 Preferably the implant is comprised of plastics
31 material.

1 More preferably the implant is comprised of
2 polypropylene.

3

4 Preferably the implant is comprised of non-
5 absorbable material.

6

7 Alternatively the implant is comprised of absorbable
8 material.

9

10 It would be advantageous if the implant was capable
11 of longitudinal extension such that it still
12 provides suitable support to the urethra during
13 periods of increased abdominal pressure, but is able
14 to move and extend in a similar fashion to tissues
15 which physiologically support the urethra.

16

17 Preferably the implant further comprises a resilient
18 zone wherein the resilient zone provides for the
19 resilient extension of the tape such that the tape
20 behaves in a similar manner to dynamic bodily
21 tissue.

22

23 Preferably the resilient zone is located in at least
24 one of the fixing zones of the implant.

25

26 Alternatively the resilient zone is interposed
27 between the fixing zone and the supporting zone.

28

29 Preferably the resilient zone of the implant is
30 capable of allowing the resilient extension of at
31 least part of the implant due to its geometric
32 design.

1

2 Alternatively the resilient zone of the implant is
3 capable of allowing resilient extension of at least
4 part of the implant due to its micro material
5 design.

6

7 More preferably the resilient zone of the implant is
8 capable of allowing the resilient extension of the
9 implant due to a combination of its geometric and
10 micro material design.

11

12 Preferably the geometric design includes multiple
13 strips of material.

14

15 More preferably the geometric design includes
16 multiple strips of material arranged into bows, the
17 bows being capable of deforming and providing
18 resilient extension to the implant.

19

20 Alternatively the geometric design comprises a
21 concertina portion such that a part of the implant
22 can extend in a direction substantially
23 perpendicular to the folds of the concertina.

24

25 In other words the implant comprises a folded
26 portion, the fold perpendicular to the longitudinal
27 axis of the implant, which allows limited extension
28 of the implant in a longitudinal direction. In an
29 extended position a folded portion is moved away
30 from a second folded position. In a closed position
31 the folded portions are brought together. Different
32 amounts of force in a longitudinal direction may be

1 required to move the concertina portion from a
2 closed to an open position.

3

4 Preferably resilient extension of a portion of the
5 implant occurs when an extension force of 1 to 5 N
6 is applied to the implant along its length.

7

8 Preferably resilient extension of a portion of the
9 implant occurs when an extension force of 2 to 3 N
10 is applied to the implant along its length.

11

12 Preferably the resilient zone provides for the
13 extension of the implant along its longitudinal
14 length of around 2 to 5 mm.

15

16 Preferably the unextended implant is of length 6 to
17 22 cm.

18

19 More preferably the unextended implant is of length
20 8 to 20 cm.

21

22 Most preferably the surgical implant is of
23 unextended length 10 to 15 cm.

24

25 Preferably each fixing zone is of at least 1 cm in
26 length and not greater than 8 cm in length.

27

28 More preferably each fixing zone is 5 cm in length.

29

30 Preferably the supporting zone is of at least 2 cm
31 in length.

32

1 Preferably the tape of the supporting zone is a
2 mesh.

3

4 Preferably the mesh is resilient.

5

6 Preferably the mesh is resilient to such an extent
7 that it mimics the physiological elasticity of
8 tissues which would normally support the urethra.

9

10 Preferably the mesh comprises strands and includes
11 major spaces and pores, the major spaces existing
12 between the strands and pores formed within the
13 strands.

14

15 Preferably the strands are formed from at least two
16 filaments.

17

18 Preferably the strands are spaced apart to form
19 major spaces of 1 to 10mm.

20

21 Preferably the strands have a diameter of less than
22 600 μ m.

23

24 Preferably the strands are arranged to form a warp
25 knit diamond or hexagonal net mesh.

26

27 Preferably the filaments comprise a plastics
28 material for example polyester or polypropylene.

29

30 More preferably the filaments are absorbable. The
31 mesh may be encapsulated by an absorbable or non

1 absorbable coating or a coating may be applied to at
2 least one side of the implant.

3
4 The surface material may be polylactic acid and the
5 core material may be polypropylene.

6
7 The mesh may be formed from biocomponent microfibres
8 comprising a core and surface material. The surface
9 material may be readily absorbable by the body while
10 the core material may remain in the body for a
11 longer period of time.

12
13 The supporting zone of the implant may be absorbable
14 at a different rate than the fixing zones of the
15 implant, for example the supporting zone may be
16 absorbed within six weeks of implantation, while the
17 fixing zones may remain for 9 months.

18
19 Preferably the fixing zones remain in the body
20 longer than the supporting zone.

21
22 The fixing zones are required to remain in the body
23 until increases in intra-abdominal pressures, for
24 example due to coughing, laughter, straining,
25 sneezing or lifting a heavy object, are transmitted
26 to the pressure compartment which includes the
27 urethra such that the increased intra-abdominal
28 pressure promotes occlusion of the urethra.

29
30 Preferably pressure transmission occurs when a
31 pubourethral neoligament forms.

32

1 Generally formation of the pubourethral neoligament
2 takes place in around 6 -9 months.

3
4 Intra-abdominal pressure transmission to the
5 pressure compartment which includes the urethra may
6 be provided by suitable placement of anchor strips
7 comprising fixing zones on either side of the
8 urethra, such that when at least one anchor strip is
9 suitably positioned on either side of the urethra,
10 even although the anchor strip does not pass under
11 the urethra and directly support the urethra using a
12 supporting element, the anchor strip provides
13 sufficient support to the urethra, by connecting the
14 intra-abdominal pressure compartment and sub
15 urethral pressure compartment such that increases in
16 intra-abdominal pressures are transmitted to the
17 urethra, promoting occlusion of the urethra during
18 periods of increased intra-abdominal pressure.

19
20 According to a further aspect of the present
21 invention there is provided at least one anchor
22 strip comprising at least one fixing zone having at
23 least one retaining means wherein in use a first
24 portion of the anchor strip is retained in the
25 tissues of the retropubic space above the endopelvic
26 fascia and a second portion of the anchor strip
27 extends into the urethral pressure compartment below
28 the endopelvic fascia and thereby supports but does
29 not pass under the urethra.

30

31 The sub urethral space is defined as a pressure
32 compartment below the endopelvic fascia.

1
2 Preferably the anchor strips are between 2 cm and 8
3 cm in length.

4
5 More preferably the anchor strips are between 4 cm
6 and 8 cm in length.

7
8 Most preferably the anchor strips are 6 cm in
9 length.

10
11 The fixing zones of the anchor strip include
12 retaining means as described herein.

13
14 Preferably the anchor strips comprise any of the

15
16 Preferably the implant is of width 0.3 to 1.7 cm.

17
18 More preferably the implant is of width 0.5 cm to
19 1.5 cm.

20
21 Most preferably the implant is of width 1.0 cm to
22 1.1 cm.

23
24 Preferably the implant is of thickness 100 μ m to
25 300 μ m.

26
27 More preferably the implant is of thickness 200 μ m.

28
29 Where the implant is reinforced, the material of the
30 implant may be of double thickness. In reinforced
31 areas of the implant the implant may be of thickness
32 between 200 μ m to 600 μ m. ~~More preferably the~~

1 reinforced areas of the implant are of thickness
2 400 μ m.

3
4 The implant is of suitable length such that a first
5 fixing zone can be secured in the tissues of the
6 retropubic space and the implant can extend from the
7 tissues of the retropubic space, pass on one side of
8 the urethra such that the supporting zone of the
9 implant passes under the urethra and a second fixing
10 zone passes on the other side of the urethra and
11 into the tissues of the retropubic space, such that
12 the second fixing zone can be secured in the tissues
13 of the retropubic space. Preferably the fixing zones
14 are positioned only as far into the tissues of the
15 retropubic space as required such that pressure
16 transmission occurs and the mid-urethra is occluded
17 at periods of raised abdominal pressure such as
18 coughing.

19
20 Typical cough pressures generated are around 0 to
21 150 cm water. Maximum cough pressures generated are
22 200 cm to 400 cm of water.

23
24 Thus during periods of raised abdominal pressure,
25 such as coughing, the bladder and urethra are pushed
26 downwards. The tape acts against this downward
27 movement of the urethra supporting the urethra and
28 causing the mid urethra to be occluded. This
29 minimises incontinence. If the tape further
30 comprises resilient zones, the resilient extension
31 of the tape during periods of raised abdominal
32 pressure cushions the urethra against the force

1 subjected to the urethra by the tape, such that the
2 urethra is supported in a more similar manner as
3 provided by physiological tissues. However, the
4 force subjected to the urethra by the tape
5 comprising resilient means, still causes the mid
6 urethra to be occluded at periods of raised
7 abdominal pressure and minimises incontinence.

8
9 It is preferable that tissue growth around and
10 through the implant occurs to integrate the implant
11 into the body.

12
13 Fibroblastic through growth around the implant
14 secures the implant in the body increasing the
15 support provided by the implant.

16
17 Preferably at least one of the fixing zones of the
18 implant is provided with means to improve
19 fibroblastic through growth into the implant.

20
21 Preferably the means to improve fibroblastic through
22 growth comprises pores which extend through the
23 fixing zone material said pores ranging in width
24 across the surface of the fixing zone from 50 μ m to
25 200 μ m.

26
27 More preferably the pores are a width of 100 μ m.

28
29 Alternatively the means to improve fibroblastic
30 through growth comprises pits, that indent at least
31 one surface of the fixing zone, but do not extend

1 through the fixing zone, the pits ranging from 50 to
2 200 μm in width.

3

4 More preferably the pits are 100 μm in width.

5

6 As a further alternative, the means to improve
7 fibroblastic through growth comprise slits that
8 extend through the fixing zone material said slits
9 being 2mm in length and 500 μm in width.

10

11 Preferably the slits are 1mm in length and 100 μm in
12 width.

13

14 More preferably the slits are 200 μm in length and
15 50 μm in width

16

17 Preferably the pits, pores or slits are distributed
18 across the complete surface of at least one of the
19 fixing zones.

20

21 Alternatively the pits, pores or slits are
22 distributed only in a particular portion of the
23 surface of at least one of the fixing zones.

24

25 Preferably the pits, pores or slits are created by
26 post synthesis treatment of at least one of the
27 fixing zones by a laser.

28

29 Alternatively the pits, pores or slits are created
30 during synthesis of at least one of the fixing
31 zones.

32

1 Where the fixing zone is comprised of plastics
2 material the pits, pores or slits may be formed by
3 the spaces of mono-filament between the waft and
4 weave of mono-filament or multi-filament yarns when
5 the filaments are woven to form a mesh.

6

7 Alternatively pits, pores or slits formed during the
8 synthesis of plastics material are formed by the
9 inter-filament spaces created when mono-filaments
10 are twisted to create multi-filaments, the multi-
11 filaments then being woven to form a mesh.

12

13 Preferably integration of the implant into the body
14 via fibrous tissue through-growth begins to occur
15 within one month of insertion of the implant in the
16 body.

17

18 More preferably integration of the implant into the
19 body via fibrous tissue through-growth begins to
20 occur within two weeks of insertion of the implant
21 in the body.

22

23 It is also advantageous that lay down of collagen
24 fibres occurs in an ordered direction to promote the
25 formation of at least one strong ordered
26 neoligament. The formation of at least one ordered
27 neoligament aids the support of the urethra provided
28 by the implant by adding mechanical strength to
29 tissue which forms around the implant.

30

1 Preferably at least one of the fixing zones is
2 provided with at least one microgroove on at least
3 one surface of the fixing zone.

4

5 Preferably at least one of the fixing zones is
6 provided with a plurality of microgrooves on at
7 least one surface of the fixing zone.

8

9 Preferably a microgroove is of width between 0.5 μm
10 to 7 μm and of depth 0.25 μm to 7 μm .

11

12 More preferably a microgroove is 5 μm in width and 5
13 μm in depth.

14

15 Preferably the plurality of microgrooves are aligned
16 such that they are substantially parallel with each
17 other.

18

19 Preferably the plurality of microgrooves are aligned
20 such that they are separated by ridges which range
21 in size between 1 μm to 5 μm in width.

22

23 More preferably the microgrooves are separated by
24 ridges of 5 μm in width.

25

26 Preferably the ridges are formed by square pillars
27 and the base of the microgroove is substantially
28 perpendicular to the square pillars.

29

1 Alternatively the ridges are formed by square
2 pillars and the base of the microgroove is bevelled
3 in relation to the pillars.

4
5 Preferably the microgrooves are present on at least
6 one surface of the fixing zone.

7
8 More preferably the microgrooves are present on a
9 plurality of surfaces of the fixing zone.

10
11 Preferably the supporting zone of the implant does
12 not comprise pores or pits.

13
14 Preferably only the surfaces of the supporting zone
15 not brought into contact with the urethra comprise
16 microgrooves.

17
18 The supporting zone is not provided with pores or
19 pits to discourage the formation of peri-urethral
20 adhesions.

21
22 Preferably at least one fixing zone is capable of
23 being moved in and out of the tissues of the
24 retropubic space by a surgeon.

25
26 Preferably movement of the fixing zone into and out
27 of the tissues of the retropubic space allows
28 adjustment of the location of the supporting zone
29 such that it passes under the urethra.

30

1 Preferably the supporting zone comprises a marker to
2 aid the suitable location of the supporting zone
3 under the urethra.

4

5 More preferably the marker is a wider portion of
6 tape of the supporting zone that indicates the
7 midpoint of the supporting zone.

8

9 The tape may comprise a reinforced portion. This is
10 advantageous as it allows the bulk of the tape to be
11 formed from a minimal mass of material. Regions of
12 the tape which require tensile strength can be then
13 strengthened appropriately.

14

15 Preferably the spine of the tape running along the
16 longitudinal axis can be reinforced.

17

18 Reinforcing may be provided by using a double
19 thickness of material.

20

21 Preferably each fixing zone comprises at least one
22 aperture adapted to receive and co-operate with a
23 tool for insertion of the implant into the body.

24

25 Preferably the tape surrounding the aperture is of
26 double thickness. This is advantageous as it
27 provides additional strength to the tape in this
28 region.

29

30 More preferably the aperture is bound by ultrasonic
31 welding.

32-

1 Preferably the aperture is located towards the end
2 of the fixing zone furthest from the supporting
3 zone.

4

5 Preferably the implant is used to support the
6 urethra.

7

8 Preferably the implant is used for treating urinary
9 incontinence or uterovaginal prolapse.

10

11 The invention also provides a tool for inserting the
12 implant into the body the tool comprising an
13 elongate shaft including a semi-blunt point at a
14 first end and a handle at a second end and holding
15 means to releasably attach the shaft to the implant.

16

17 Preferably the tool can be used to insert implants
18 comprising a supporting zone or anchor strips.

19

20 Preferably the elongate shaft is curved or bent,
21 through an angle of approximately 30°.

22

23 Preferably the elongate shaft of the tool is of
24 length 6 to 15 cm.

25

26 More preferably the elongate shaft of the tool is 8
27 cm in length.

28

29 Preferably the elongate shaft of the tool is between
30 2-3 mm in diameter.

31

1 Preferably the holding means comprises a recess
2 extending from the semi-blunt point of the elongate
3 shaft the recess capable of receiving a portion of
4 the implant.

5
6 The point of elongate shaft comprising the recess
7 may be offset such that a first portion forming a
8 wall of the recess is longer than a second portion
9 forming the opposite wall of the recess. This is
10 advantageous as the longer portion of the shaft on
11 one side of the recess aids mounting of the tape on
12 the tool.

13
14 Preferably the recess is angled to twist an implant
15 received by the recess along its longitudinal length
16 such that the longitudinal edges of the fixing zone
17 of the implant are directed away from the bladder.

18
19 Twisting of the implant such that the edges of the
20 fixing zone are directed away from the bladder
21 minimises medial presentation of the retaining means
22 to the bladder.

23
24 Alternatively the holding means comprises an
25 abutment located toward the first end of the
26 elongate shaft of the tool wherein the semi-blunt
27 point of the elongate shaft is capable of being
28 passed through the implant and the abutment is
29 capable of hindering movement of the implant down
30 the length of the shaft toward the second end of the
31 elongate shaft.

32

1 Preferably the tool is comprised of plastics
2 material.

3
4 Alternatively the tool is comprised of surgical
5 steel.

6
7 Preferably the handle is circular in shape and is
8 mounted perpendicular to the curvature at the second
9 end of the elongate shaft.

10
11 According to a further aspect of the present
12 invention there is provided a method of supporting
13 the urethra comprising the steps of;

14
15 introducing an implant into a least one
16 incision made on the upper wall of the vagina,
17
18 inserting a first end of the implant behind the
19 first side of the urethra,

20
21 locating a first fixing zone into the tissues
22 of the retropubic space without penetrating the
23 rectus sheath,

24
25 inserting a second end of the implant behind a
26 second side of the urethra, and

27
28 locating a second fixing zone into the tissues
29 of the retropubic space without penetrating the
30 rectus sheath, such that the supporting zone
31 passes under the urethra.

32

1 Preferably the ends of the implant are located in
2 the retropubic space above the endopelvic fascia.

3

4 Preferably the method further includes the step of
5 moving the retaining means from an inserting
6 position to a retaining position.

7

8 Preferably the method of supporting the urethra is
9 used in treating urinary incontinence or
10 uterovaginal prolapse.

11

12 According to a further aspect of present invention
13 there is provided a method of transmitting intra-
14 abdominal pressure to the urethra comprising the
15 steps of

16

17 introducing an anchor strip into at least one
18 incision made on the upper wall of the vagina;

19

20 inserting a first portion of the anchor strip
21 behind the first side of the urethra;

22

23 locating a first portion including a fixing
24 zone into the tissues of the retropubic space
25 above the endopelvic fascia without penetrating
26 the rectus sheath;

27

28 locating a second portion of the anchor strip
29 alongside the urethra in the suburethral
30 pressure compartment below the endopelvic
31 fascia ;

1 inserting a second anchor strip behind a second
2 side of the urethra;

3
4 locating a first portion including a fixing
5 zone of the second anchor strip into the
6 tissues of the retropubic space without
7 penetrating the rectus sheath; and

8
9 locating a second portion of the second anchor
10 strip along side the urethra in the suburethral
11 pressure compartment below the endopelvic
12 fascia.

13
14 Preferably at least one anchor strip is introduced
15 through two small incisions.

16
17 Preferably the method further includes the step of
18 moving retaining means from an inserting position to
19 a retaining position.

20
21 Preferably the anchoring strip is used to treat
22 urinary incontinence or uterovaginal prolapse.

23
24 Preferably the method of enabling transmission of
25 the intra-abdominal pressure to the urethra is used
26 in treating urinary incontinence or uterovaginal
27 prolapse.

28
29 Embodiments of the present invention will now be
30 described by way of example only, with reference to
31 the accompanying drawings in which;

1 Figure 1 shows a diagrammatic view of the
2 implant;

3
4 Figure 2 shows a diagrammatic side view of the
5 implant;

6
7 Figure 3 shows retaining means which may be
8 present at the fixing zone;

9
10 Figure 3b shows an illustration of one
11 embodiment of the tape in cross section;

12
13 Figure 3c shows an illustration of a further
14 embodiment of the tape;

15
16 Figure 4 shows an illustration of a further
17 embodiment of the tape wherein the supporting
18 zone is formed from mesh;

19
20 Figure 5 shows a diagrammatic view of the
21 retropubic space, related to needle passage for
22 any pubo-vaginal sling;

23
24 Figure 6 shows an illustration of an
25 introducing tool;

26
27 Figure 7 shows an illustration of a further
28 embodiment of an introducing tool wherein the
29 point of the tool is offset to aid insertion of
30 the implant into the recess of the tool;

31

1 Figure 8 shows an illustration of a further
2 embodiment of an introducing tool;

3

4 Figure 9 shows an illustration of the position
5 of the tape in relation to the bladder taken
6 from a superior view; and

7

8 Figures 10a and 10b show alternative
9 embodiments of retaining means.

10

11 Figure 11 shows anchor strips positioned on
12 either side of the urethra in the suburethral
13 space below the endopelvic fascia and extending
14 into the retropubic space above the endopelvic
15 fascia.

16

17 Referring to figure 1 in one embodiment the surgical
18 implant is a flat tape 2 which has a supporting zone
19 4 interposed between two fixing zones 6, the fixing
20 zones being discrete zones of fixation extending
21 from the supporting zone 4 to the first 8 and second
22 10 ends of the tape 2 respectively. Apertures 11
23 extend through the tape 2 approximate to the first
24 and second ends of the tape 2. These apertures 11
25 are of suitable size to allow a portion of an
26 introducing tool to be passed through the apertures
27 11.

28

29 The implant may be 14 cm in length and 1 cm in
30 width, the supporting zone 4 being around 4 cm in
31 length such that it is able to pass under the
32 urethra.

1
2 In this example, the implant is made from flat
3 polymer tape. The tape may be comprised of
4 polypropylene. Alternatively all or portions of the
5 tape can be mesh material. The tape need not be
6 entirely flat and may have be curved in one or more
7 directions for example to aid insertion of the tape
8 or to ensure that the fixing zone does not interfere
9 with elements contained in the retropubic space such
10 as the bladder.

11
12 As shown in figure 3 the longitudinal edges 30, 32
13 of the fixing zone 6 may be tapered such that the
14 width of the fixing zones increases from the first
15 and second ends 8, 10 of the fixing zones to the
16 supporting zone. The tapered nature of the fixing
17 zones 6 minimises disruption of the tissue of the
18 retropubic space during placement of the tape 2 by
19 the surgeon. The increasing width forms an
20 arrowhead shape, the longitudinal edges of the tape
21 extending from a point at a first and second end of
22 the tape to the longitudinal edges of the support
23 zone. The longitudinal edges extending from the
24 point to the supporting zone may be serrated or
25 notched to provide projections 22 which in use
26 extend into the tissues of the retropubic space.
27 The projections 22 provide multiple points of
28 contact between the tape 2 and the tissues of the
29 retropubic space at multiple planes in the tissue.

30
31 The projections 22 of the retaining means 20 in the
32 embodiment shown in figure 3 ~~are curved~~ such that

1 they extend from the longitudinal axis such that in
2 use the projections 22 are not medially presented to
3 the bladder 42 which lies antero-medially in
4 respect to the passage of tape 2 in the body.

5
6 Further as shown in figure 3b the tape 2 may be of
7 curved or of convex construction such that retaining
8 means 20 such as the projections 22 face in a
9 direction opposite or away from the bladder 42 in
10 use. The curvature of the tape 2 therefore ensures
11 that the projections 22 lie postero-laterally of the
12 antero-medial bladder position. This positioning
13 minimises the possibility of bladder erosion by the
14 tape 2 following placement.

15
16 The tape 2 of the supporting zone has smooth
17 longitudinal edges to avoid adhesion of the
18 supporting zone of the tape to the urethra.

19
20 This is advantageous as it discourages the formation
21 of peri-urethral adhesions.

22
23 The polypropylene tape 2 of the fixing zone 6
24 comprises pores 12, ranging in width from 50µm to
25 200µm, that extend through a first surface 14 to a
26 second opposite surface 16 of the tape 2. The pores
27 12 may be formed by post synthesis treatment of the
28 fixing zones of the tape 2 with a laser.

29
30 The pores 12 promote fibroblastic through-growth and
31 lay down of tissue around and through the tape 2.

1 This aids integration of the fixing zone of the tape
2 2 to the tissue of the retropubic space.

3

4 The pores 12 may alternatively be created by post
5 synthesis treatment of the fixing zones 6 of the
6 tape 2 by a laser.

7

8 In addition to the pores 12, in the embodiment shown
9 the fixing zone also comprises microgrooves 18 of
10 width $5\mu\text{m}$ and of depth $5\mu\text{m}$. These microgrooves 18
11 are shown present on one surface 14 of the fixing
12 zone of the tape 2, but may also be present on the
13 opposite surface. In the embodiment shown the
14 microgrooves 18 are aligned such that they are
15 substantially parallel with each other and separated
16 by ridges 24 of around $5\mu\text{m}$ in width. It can be
17 appreciated that the microgrooves may be arranged to
18 create alternative surface patterns on the tape,
19 depending on the direction of the laydown of tissue
20 preferred.

21

22 The ridges 24 are formed by square pillars, the base
23 26 of the microgroove 18 being substantially
24 perpendicular to the square pillars.

25

26 Microgrooving can promote orientation and alignment
27 of proliferating fibroblasts on the surface 14 of
28 the tape 2 of the fixing zone 6 and promotes axial
29 alignment of collagen fibres and formation of at
30 least one strong ordered neoligament. The
31 orientation and alignment of the proliferating cells
32 adds mechanical strength to the tissue which form-

1 around the tape such that these tissues support the
2 urethra.

3
4 The supporting zone 4 of the tape 2 is preferably
5 not provided with pores or pits to discourage the
6 formation of peri-urethral adhesions. Micro-
7 grooving is preferably provided only on the surfaces
8 of the supporting zone not brought into contact with
9 the urethra when the implant is in use.

10
11 As discussed, urinary incontinence may be caused if
12 the pelvic floor muscles and connective tissue
13 cannot support the bladder neck and mid-urethra,
14 when pressure on the bladder is exerted from the
15 diaphragm. Increased intra-abdominal pressure may
16 occur at times such as coughing. The increased
17 abdominal pressure results in the urethra descending
18 from its normal position and failing to retain its
19 seal, permitting urine to escape.

20
21 Previous apparatus and methods used for locating an
22 implant such that the implant hangs loosely under
23 the urethra have generally required that the implant
24 be suspended from either the lower abdominal wall,
25 the rectus sheath or other defined anatomical
26 support structures. The suspension of an implant
27 from defined anatomical support structure was
28 thought necessary as the tissues of the retropubic
29 space and endopelvic fascia were not deemed to
30 provide enough resistance to allow appropriate
31 location of an implant such that suitable support
32 ~~would be provided to occlude the mid-urethra at~~

1 periods of raised abdominal pressure, by coughing or
2 the like.

3
4 Surprisingly the Applicant has determined that
5 suitable support can be provided by the tissues of
6 the retropubic space, if fixation of the implant is
7 achieved in the tissues of the retropubic space.
8 Due to the tissue make up of the retropubic space,
9 it was not previously considered that suitable
10 fixation could be achieved in the retropubic space.
11 Further it was not considered that suitable pressure
12 transmission would be achieved to occlude the
13 urethra, using a tape suspended from the tissue of
14 the retropubic space, doing periods of increased
15 abdominal pressure.

16
17 As shown in figure 7 the retropubic space 40 is an
18 extraperitoneal tissue space lying behind the pubic
19 bone. The retropubic space is defined by an antero-
20 -superior boundary which is the peritoneum and
21 rectus sheath 44 and an interior boundary of
22 endopelvic fascia 46. The space defined by these
23 boundaries is medially filled by the bladder 42, the
24 urethra 48, fibro-fatty tissue and blood vessels.
25 The blood vessels of the retropubic space generally
26 become larger both in a superior and lateral
27 direction within the retropubic space. The
28 retropubic space approximately extends 8 cm from the
29 endopelvic fascia to the rectus sheath, this
30 distance varying by around 2 cm depending on the
31 individual. The retropubic space comprises the same
32 pressure compartment as the abdomen.

1
2 To locate the supporting zone 4 such that it passes
3 loosely under the urethra 60 it is required that the
4 fixing zones 6 are fixed in the tissues of the
5 retropubic space 40 with as little tissue invasion
6 as possible, but such that pressure transmission to
7 the tape is maintained. A number of different
8 retaining means can be envisaged including a
9 christmas tree design (a), a brush (b), a fish hook
10 (c), a triple hook (d), an umbrella (e), one or more
11 rods with memory (f), a corkscrew (g), an inflatable
12 balloon (h), an inflatable flat star (i), a bear
13 trap (j), a bulldog clip (k), a mesh cylinder (l), a
14 buckie ball (m), a staple (n), a barbed portion of
15 tape (o), a sponge (p) or fibre entanglement method
16 (q) to secure the fixing zones of the surgical
17 implant into the tissues of the retropubic space.
18 Examples of these embodiments are shown in figures
19 10a and 10b. It should also be noted that a
20 plurality of retaining means may be located alone or
21 in combination along a substantial part of the
22 fixing zone.

23
24 As shown in figure 11 support to the urethra can be
25 suitably gained by locating at least one anchor
26 strip 80 on either side of the urethra such that a
27 first portion of the anchor strip 82 extends into
28 the retropubic space above the endopelvic fascia and
29 is retained therein and a second portion of the
30 anchor strip is located in the suburethral pressure
31 space below the endopelvic fascia such that
32 increases of intra-abdominal-pressure are

1 transmitted to the pressure compartment containing
2 the urethra and during periods of increased intra-
3 abdominal pressure the urethra is occluded
4 minimising incontinence. Retention of the first end
5 of the anchor strip in the retropubic space is
6 provided by retaining means.

7
8 In a first embodiment, retaining means 20 are a
9 plurality of projections 22 extending laterally from
10 the longitudinal axis of the implant. These
11 projections 22 are arranged along a substantial
12 portion of the length of the fixing zone 6 such that
13 when located in the tissues of the retropubic space
14 they provide resistance at multiple levels within
15 the fibro-fatty soft tissue and blood tissues of the
16 para-urethral tunnel in a direction opposite to that
17 in which the fixing zone 6 of the tape 2 is
18 introduced into the tissues. This minimises
19 movement of the tape out of the tissues of the
20 retropubic space, even when a force is applied to
21 the tape which acts to push or pull the tape out of
22 the retropubic space.

23
24 Due to the multiple layers of fixation that can be
25 achieved using the plurality of retaining means 20
26 along a substantial length of the fixing zone 6 it
27 is not necessary to insert the fixing zone through
28 the rectus sheath 44. This of significant advantage
29 to the patient as puncture of the retropubic space
30 requires considerable force by the surgeons and also
31 requires larger, heavier needles leading to patient
32 trauma... ~~In addition the tissues around the rectus~~

1 sheath are innervated leading to pain if these are
2 punctured. The fixing zone 6 is movable within the
3 tissues of the retropubic space by the surgeon
4 during placement of the tape 2 to allow suitable
5 positioning of the supporting zone 4 under the
6 urethra. The retropubic space maximum sagittal
7 length typically ranges between 6 cm to 10 cm
8 defined by the boundaries discussed, thus the fixing
9 zone 6 may be inserted at various positions within
10 the fibro-fatty tissue of the retropubic space. The
11 sagittal plane is that down the longitudinal length
12 of the body. The approximate 8 cm length is the
13 typical length of the retropubic space at the course
14 of the paraurethral tunnel. Towards the pubic bone
15 the retropubic space may be only 3 cm in length.
16 This provides a means of adjustment of the position
17 of the supporting zone 4 in relation to the urethra.
18 The tape 2 may be moved by a surgeon during
19 placement of the tape in the body into and out of
20 the tissues of the retropubic space to suitably
21 locate the supporting zone in relation to the
22 urethra.

23

24 As shown in figure 3 the projections 22 which form
25 the retaining means 20 are curved such that the
26 points 24 of the projections 22 are directed away
27 from the supporting zone and the bladder.

28

29 In a further second embodiment of the implant as
30 shown in figure 3c, the implant further comprises
31 resilient zones 7 interposed between the fixing

32 ~~---zones 6 and the supporting zone 4.~~

1

2 The two resilient zones 7 may comprise a geometric
3 design of several strip portions conjoined at a
4 first end to the supporting means and at a second
5 opposite end to fixing means on the implant.

6

7 When not under tension these strip portions of tape
8 material are bow shaped and are arranged such that
9 they form a series of alternate and side by side
10 convex and concave strips arranged in substantially
11 the same plane as the tape.

12

13 On application of an extending force of up to 3N to
14 the tape along its length, the tape can show 2-3 mm
15 of extension, as the bowshaped portions of the tape
16 are pulled into straight strips, the ends of the
17 bowshaped strips being brought together, enabling
18 extension of the tape. The movement of the tape
19 from the resting bowshape into the tensioned
20 straight strips of tape allows the tape to
21 resiliently extend along its length.

22

23 The maximum length to which the tape can be
24 extended, is when the convex and concave portions of
25 the tape are pulled such that these strips are
26 brought into alignment with the longitudinal axis of
27 the implant. Depending on the nature and length of
28 the bow shaped portion, the extended length and the
29 force required to promote extension of the tape can
30 be controlled.

31

1 On release of the extending force these now
2 straightened strips of tape of the resilient zone
3 return to their previous non-extended bowshape
4 causing the tape to resiliently return to its non-
5 extended length.

6
7 The ability of the tape to show limited extension
8 following the application of an extending force
9 means that the tape more accurately mimics the
10 movement of dynamic bodily tissue.

11
12 In order that the bowshape like portions of the tape
13 can be pulled such that they are straightened, the
14 material of the tape must be resilient to an extent,
15 The amount of resilience of the material will
16 influence the resilience of the tape to an extending
17 force. In addition, the micro material design of
18 the material of the tape can be used to limit or
19 promote the resilience of the tape to an extending
20 force.

21
22 Micro material design includes the way in which the
23 tape material is woven, knitted or formed such that
24 the tape material is resilient and allows extension
25 along a particular axis.

26
27 Different geometric designs to allow extension of
28 the implant in particular directions can be
29 envisaged, for example folding of the tape would
30 provide a concertina design which would allow
31 resilient extension of the table in a direction
32 substantially perpendicular to the folding.

1
2 This further embodiment of the implant shown in
3 figure 3C also shows elongate slits in the fixing
4 means of the tape. These elongate slits are of 1 mm
5 in length and 50 to 100 μ m in width. The elongate
6 slits allow fibroblast through growth into the tape,
7 securing the tape to the tissues.

8
9 As shown in figure 3c the implant can further
10 comprise a protrusion of fabric 9 which extends
11 laterally from the longitudinal edges of the
12 supporting zone member to indicate to the surgeon
13 the midpoint in the length of the tape to aid the
14 surgeon in locating the implant under the urethra.

15
16 The inclusion of the resilient zones within the
17 implant, shown in figure 1, provides the implant
18 with limited extension following location of the
19 fixing zones in the retropubic tissues on either
20 side of the urethra. As the supporting zone which
21 lies underneath and supports the urethra can show
22 limited extension, the urethra is therefore
23 supported in a more similar manner to that as when
24 it is supported by dynamic bodily tissue.

25
26 The embodiments of the implant described herein may
27 be suitably located in the tissues of the retropubic
28 space using an introducing tool.

29
30 As shown in figure 6 one embodiment of the
31 introducing tool 50 comprises a handle 52, an
32 ~~elongate shaft 54 and a semi-blunt point 56, the~~

1 handle 52 being located at a first end 58 of the
2 elongate shaft 54 and the semi-blunt point 56 being
3 located at a second end 60 of the elongate shaft 54.
4 The elongate shaft 54 is curved through an angle of
5 approximately 30° to facilitate positioning of the
6 fixing zone 6 of the implant in the tissues of the
7 retropubic space of the human body from an incision
8 in the upper wall of the vagina. A narrowed portion
9 62 of the elongate shaft 54 extends from the semi-
10 blunt point 56 toward the handle 52. An abutment 64
11 is formed where the shaft widens from the narrowed
12 portion. The narrowed portion of the tool is able
13 to be passed through the aperture 11 present in the
14 fixing zones 6 of the tape 2. The abutment 64
15 prevents the movement of the tape 2 down the full
16 length of the elongate shaft 54 such that the tape 2
17 is retained on the narrowed portion 62 of the
18 elongate shaft 54, the semi-blunt point 56 extending
19 through the aperture 11 in the tape 2.

20
21 An alternative embodiment of the tool, shown in
22 figure 7 comprises a recess 70 which extends from
23 the semi-blunt point 56, the recess being adapted to
24 receive a fixing zone 6 of the implant. The recess
25 may be angled or offset such that when the fixing
26 zone of the tape is positioned in the recess 70 of
27 the tool, the tape is twisted along its longitudinal
28 length such that on placement of the tape within the
29 tissues of the retropubic space the projections of
30 the fixing zone face postereo-laterally of the
31 antero-medial bladder position. Figure 8 shows an

1 illustration of the direction of the retaining means
2 in relation to the bladder.

3

4 Further the tip of the tool may be offset such that
5 one portion forming the wall of the recess extends
6 further than the other portion forming the recess.
7 This allows easier positioning of the tape into the
8 recess.

9

10 The introducing tool 50 may be comprised of any
11 suitable material. In the embodiments shown the
12 tool 50 is 8 cm in length and 2-3 mm in diameter and
13 is comprised of hard plastic. The tool may be
14 disposable or capable of being sterilised.

15

16 With regard to the first embodiment of the tool, in
17 use the semi-blunt point 56 is passed through the
18 aperture 11 in the tape 2 such that the tape 2 rests
19 on the abutment 64 preventing the tape 2 from moving
20 further down the elongate shaft 54 of the tool 50.

21 The tape 2 is rolled about its longitudinal axis
22 such that the edges 30,32 are brought toward each
23 other. The tape 2 is restrained in this rolled
24 position. The tape 2 may be restrained by the
25 surgeon or by an envelope placed over the rolled
26 tape. An envelope placed over the rolled tape may
27 comprise a medial defect, which allows removal of
28 the envelope when the tape is suitably positioned,
29 by pulling the tape through the defect in the
30 envelope.

31

1 The rolled fixing zone 6 of the tape 2 is inserted
2 via an incision in the anterior vaginal wall, past
3 one side of the urethra and into the retropubic
4 space. Ideally insertion of the fixing zone 6 into
5 the tissues of the retropubic space should be as
6 limited as possible, but sufficient to allow
7 suitable location of the fixing zone 6 and adequate
8 pressure transmission to allow occlusion of the
9 urethra. Following insertion of the first end of
10 the tape 2, the fixing zone 6 may be moved within
11 the tissues of the retropubic space by the surgeon
12 such that the fixing zone 6 is suitably located in
13 the fibro-fatty soft tissue. Withdrawal of the
14 introducing tool 50, described above, causes the
15 narrowed portion 62 of the tool 50 to be retracted
16 from the aperture 11 of the tape 2. This causes
17 release of the tape 2 from the tool. The tape may
18 also be released from its restrained position by the
19 surgeon. As the implant is formed from resilient
20 material, which has memory, release of the implant
21 from its restrained rolled position causes the
22 longitudinal edges 30,32 to expand outwards, away
23 from each other, from the rolled position such that
24 the retaining means, the plurality of projections 22
25 at multiple layers, are pushed into the surrounding
26 tissues of the retropubic space.

27
28 This causes projections to enter the retropubic
29 tissue at multiple levels. Although the force
30 required to move one projection through the tissue
31 of the retropubic space may be small, the multiple
32 ~~...projections, cause an additive effect and increase--~~

1 the force required to move the tape from the tissue
2 of the retropubic space.

3

4 With regard to the second embodiment of the
5 introducing tool discussed, in use, an aperture 11
6 in the tape 2 is passed over the semi-blunt point 56
7 such that a portion of fixing zone 6 of the tape 2
8 is retained in the recess 70, while the rest of the
9 tape 2 comprising the supporting zone and a second
10 fixing zone lies along the longitudinal length of
11 the tool. As discussed, the recess 70 of the
12 introducing tool may be angled such that the fixing
13 zone 6 retained within the recess 70 is orientated
14 such that on placement of the fixing zone 6 in the
15 tissues of the retropubic space the retaining means
16 20 of the fixing zone 6 face away from the bladder
17 to minimise the risk of erosion of the bladder by
18 the retaining means.

19

20 Introduction of the implant into the body using the
21 second embodiment of the tool described is similar
22 to that previously described. Release of the fixing
23 zone 6 of the tape 2 from the recess 70 is performed
24 by withdrawal of the tool.

25

26 The serrated arrowhead shape of the fixing zone of
27 the embodiment described, means that as the fixing
28 zone is pushed into a suitable location by the
29 surgeon using the introducing tool, the distortion
30 of the tissue in which the fixing zone is to be
31 placed is minimised. This ensures that the
32 ~~retaining means of the fixing zone is provided with~~

1 suitable tissue in which to obtain multi-level
2 fixation. The fixation being of adequate tensile
3 strength against cough until fixation of the implant
4 by tissue through-growth occurs.

5
6 Following insertion and suitable placement of the
7 fixing zone 6 of the tape 2, penetration of the
8 fibro-fatty tissue by the multiple projections 22
9 occurs at multiple levels in the tissue and
10 increases the grip of the retaining means 20 on the
11 fibro-fatty soft tissue of the retropubic space. As
12 the entry of the retaining means 20 is active and
13 not passive, actively inserting the retaining means
14 20 into the tissue, the gripping effect of the
15 plurality of the projections 22 is increased.

16 A second fixing zone comprising retaining means 20
17 as described for the first fixing zone is rolled
18 such that the longitudinal edges 30,32 are brought
19 toward each other. The implant is restrained in
20 this rolled position and inserted through the same
21 incision in the vaginal wall as the first fixing
22 zone, past the other side of the urethra to that of
23 the first fixing zone and the rolled second fixing
24 zone 6 released to allow the retaining means to grip
25 the tissues of the retropubic space. The supporting
26 zone 4 of the tape 2 being suitably located and held
27 in position by the fixing zones 6 under the urethra
28 to provide support to the urethra. In such a
29 suitable portion the supporting zone is able to
30 occlude the urethra at periods of increased
31 abdominal pressure and thus minimise urinary
32 incontinence.

1

2 In a second embodiment of the present invention
3 retaining means are provided by glue.

4

5 Suitable glue such as cyanoacrylate glue or butyl
6 acrylate glue may be applied to the fixing zone 6 of
7 the tape 2. The glue is not applied to the
8 supporting zone 4 of the tape 2, to ensure that the
9 supporting zone 4 does not bind to the urethra.

10

11 In use cyanoacrylate glue is applied along a
12 substantial length of a first fixing zone 6 of the
13 tape 2 and this first fixing zone 6 is inserted
14 through an incision in the anterior vaginal wall,
15 past one side of the urethra into the retropubic
16 space. Following insertion of the first end 8 of
17 the implant such that the fixing zone 6 is suitably
18 located in the fibro-fatty soft tissue of the
19 retropubic space, the tape 2 is held to enable an
20 adhesive bond to form between the fixing zone 6 of
21 the tape 2 and the tissues of the retropubic space.
22 As the glue is applied along a substantial length of
23 the first fixing zone 6, the first fixing zone 6
24 adheres to the fibro-fatty soft tissue of the
25 retropubic space at multiple layers providing
26 suitable resistance.

27

28 Cyanoacrylate glue can then be applied along a
29 substantial portion of a second fixing zone 6. The
30 second fixing zone 6 can then be inserted through
31 the same incision in the vaginal wall and past the
32— other side of the urethra—such that the supporting

1 zone 4 is located to provide support to the urethra.
2 The glue may be provided within dissolvable spheres
3 which will coat the glue during entry of the tape
4 into the body, the coating dissolving when the
5 implant is suitably located such that the glue can
6 adhere the tape to surrounding tissues.

7
8 The glue to adhere the fixing zones of the implant
9 to the tissues of the retropubic space may be
10 provided in capsules or releasable containers
11 mounted or attached to the implant. Once at least
12 one of the fixing zones of the implant has been
13 suitable positioned in the tissues of the retropubic
14 space the capsules containing the glue can be burst
15 using suitable means. For example, the capsule may
16 be burst using a sharp point present on the
17 introducing tool. Alternatively withdrawal of the
18 introducing tool from the retropubic tissues may
19 rupture or burst such capsule or promote the opening
20 of the releasable containers such that the glue
21 contained in the capsule or container is able to
22 adhere the fixing zone of the implant to the
23 surrounding tissues.

24
25 Where glue is use to adhere the fixing zone of the
26 implant to the surrounding tissue, the fixing zone
27 may be smaller than the dimensions listed above.
28 Use of glue to fix the implant in the tissues of the
29 retropubic space provides multilevel fixation of the
30 implant. Other methods or means to allow release or
31 activation of the glue, for example heat, can be
32 envisaged by those skilled in the art.

1
2 Further embodiments of retaining means can be
3 envisaged such as swelling hydrogels such as
4 gelatin, polysaccharides or Hyaluronic acid. These
5 may be applied to the fixing zone 6 of the implant,
6 such that following introduction of the fixing zone
7 6 of the implant into the body the hydrogel expands,
8 providing resistance in a direction opposite to that
9 in which the fixing zone 6 of the implant is
10 introduced into the tissues, suitably locating the
11 supporting zone 4 to support the urethra.

12
13 In addition retaining means may be substances which
14 have properties changed by heat, cold or light that
15 may be applied to the fixing zone 6 of the implant
16 such that on suitable treatment of the implant, the
17 fixing zone 6 of the implant becomes suitably fixed
18 in tissues of the retropubic space.

19
20 The length of the implant of the present invention
21 is considerably less than that described in the
22 prior art, which is typically 25 to 28 cm in length.
23 This is of considerable advantage as the amount of
24 foreign material placed in the body is reduced,
25 decreasing the risk of inflammation and other
26 problems associated with leaving foreign material in
27 the human body for periods of time.

28
29 In addition as the present invention does not
30 require the highly innervated and tough structures
31 of the lower abdomen wall or rectus sheath to be
32 ~~punctured, which require considerable force to be~~

1 applied by the surgeon, to enable location and
2 fixing of the implant the trauma suffered by the
3 patient is considerably reduced. Due to the
4 decreased trauma suffered by the patient the above
5 procedure may be carried out under local anaesthetic
6 in an outpatient or office setting.

7
8 As a greater number of major blood vessels are found
9 located in the retropubic space toward the rectus
10 sheath, suitable placement of the anchor lower in
11 the retropubic space minimises damage to blood
12 vessels, reducing the amount of blood which might be
13 lost by the patient.

14
15 Further, as there is not a requirement to anchor the
16 fixing zone of the tape toward the rectus sheath,
17 staying medially the tape can be placed lower and
18 more laterally in the retropubic space toward the
19 endopelvic fascia this reduces the chance of damage
20 to anatomical structures such as the bladder. In
21 view of the decreased risk of damaging the bladder
22 the described procedure may be performed without the
23 need for per operative cystoscopy. This reduces the
24 overall time taken to perform the procedure, further
25 reduces the pain and trauma suffered by the patient
26 and reduces the expense of the procedure.

27

28

29

1 CLAIMS

2

3 1. A surgical implant for supporting the urethra,
4 the implant including at least two fixing zones
5 and a supporting zone, the supporting zone
6 being interposed between the fixing zones and
7 the fixing zones each having at least one
8 retaining means for anchoring the fixing zones
9 in the tissues of the retropubic space without
10 penetrating the rectus sheath such that in use
11 the supporting zone passes under the urethra.

12

13 2. A surgical implant for supporting the urethra
14 comprising an anchor strip the anchor strip
15 comprising at least one fixing zone having at
16 least one retaining means wherein in use a
17 first portion of the anchor strip is retained
18 in the tissues of the retropubic space above
19 the endopelvic fascia and a second portion of
20 the anchor strip extends into the urethral
21 pressure compartment below the endopelvic
22 fascia and thereby supports but does not pass
23 under the urethra.

24

25 3. A surgical implant as claimed in claim 1
26 wherein the supporting zone is comprised of
27 mesh.

28

29 4. A surgical implant as claimed in any preceding
30 claim wherein the retaining means are moveable
31 from an inserting position to a retaining
32 position.

- 1
- 2 5. A surgical implant as claimed in claim 4
- 3 wherein the retaining means is at least one
- 4 projection which can project from the implant
- 5 into the tissues of the retropubic space in at
- 6 least one plane the projection being moveable
- 7 from a collapsed position to an extended
- 8 position.
- 9
- 10 6. A surgical implant as claimed in any preceding
- 11 claim wherein the retaining means is glue.
- 12
- 13 7. A surgical implant as claimed in claim 6
- 14 wherein the glue is cyanoacrylate glue.
- 15
- 16 8. A surgical implant as claimed in any preceding
- 17 claim wherein the fixing zone has a pointed end
- 18 at a first end, a base portion at a second end,
- 19 wherein longitudinal edges extend between the
- 20 pointed end and the base and the longitudinal
- 21 edges are notched to provide a row of
- 22 projections extending outward from the
- 23 longitudinal edges.
- 24
- 25 9. A surgical implant as claimed in any preceding
- 26 claim wherein the implant is comprised of
- 27 plastics material.
- 28
- 29 10. A surgical implant as claimed in any preceding
- 30 claim wherein the implant is comprised of
- 31 absorbable material.
- 32

- 1 11. A surgical implant as claimed in claims 1 or 3
2 to 10 wherein the material of the supporting
3 zone is more quickly absorbed by the body than
4 the material of the fixing zones.
5
- 6 12. A surgical implant as claimed in any preceding
7 claim wherein the implant further comprises at
8 least one resilient zone wherein the resilient
9 zone provides for resilient extension of the
10 implant along its longitudinal axis.
11
- 12 13. A surgical implant as claimed in claim 12
13 wherein the resilient zone is interposed
14 between the fixing zone and the supporting
15 zone.
16
- 17 14. A surgical implant as claimed in any preceding
18 claim wherein the unextended length of the
19 implant is 6 to 22 cm.
20
- 21 15. A surgical implant as claimed in any of claims
22 2, 4 to 10 or 12 wherein the unextended length
23 of the implant is between 4 to 8 cm.
24
- 25 16. A surgical implant as claimed in any preceding
26 claim wherein the implant is of width 0.3 cm to
27 1.7 cm.
28
- 29 17. A surgical implant as claimed in any preceding
30 claim wherein the implant is of thickness 100
31 μm to 600 μm .
32.

- 1 18. A surgical implant as claimed in any preceding
2 claim wherein at least one of the fixing zones
3 comprises pores which extend through the fixing
4 zone material.
5
- 6 19. A surgical implant as claimed in any preceding
7 claim wherein at least one of the fixing zones
8 comprises pits that indent at least one surface
9 of the fixing zone, but do not extend through
10 the fixing zone.
11
- 12 20. A surgical implant as claimed in any preceding
13 claim wherein at least one of the fixing zones
14 comprise slits that extend through the fixing
15 zone material.
16
- 17 21. A surgical implant as claimed in any preceding
18 claim wherein at least one microgroove is
19 provided on at least one fixing zone.
20
- 21 22. A surgical implant as claimed in claim 21
22 wherein a microgroove is between 0.5 μm to 7 μm
23 in width and 0.25 μm to 7 μm in depth.
24
- 25 23. A surgical implant as claimed in any one of
26 claims 1, 3 to 22 wherein the supporting zone
27 comprises a marker to aid the suitable location
28 of the supporting zone under the urethra.
29
- 30 24. A surgical implant as claimed in any preceding
31 claim wherein each fixing zone comprises at

1 least one aperture adapted to receive a tool
2 for insertion of the implant into the body.

3

4 25. Use of an implant as claimed in any preceding
5 claim to support the urethra.

6

7 26. Use of an implant as claimed in any preceding
8 claim for treating urinary incontinence or
9 uterovaginal prolapse.

10

11 27. A tool for inserting the implant as claimed in
12 any preceding claim the tool comprising an
13 elongate shaft including a semi-blunt point at
14 a first end and holding means to releasably
15 mount the surgical implant on the shaft.

16

17 28. A tool as claimed in claim 27 wherein the
18 holding means comprises a recess extending from
19 the semi-blunt point of the elongate shaft the
20 recess capable of receiving a portion of the
21 surgical implant.

22

23 29. A tool as claimed in claim 28 wherein the
24 recess is angled to twist a surgical implant
25 received by the recess along its longitudinal
26 length such that the longitudinal edges of the
27 fixing zone of the implant are directed away
28 from the bladder.

29

30 30. A tool as claimed in claims 28 and 29 wherein
31 the recess is offset such that a first portion
32 forming a wall of the recess is longer than a...

1 second portion forming an opposite wall of the
2 recess.

3
4 31. A tool as claimed in claim 27 wherein the
5 holding means comprises an abutment located
6 toward the first end of the elongate shaft
7 wherein the semi-blunt point of the elongate
8 shaft is capable of being passed through the
9 surgical implant and the abutment is capable of
10 hindering movement of the surgical implant down
11 the length of the shaft toward the second end
12 of the elongate shaft.

13
14 32. A method of supporting the urethra comprising
15 the steps of;
16
17 introducing a surgical implant as claimed in
18 any of claims 1, 3 to 24 into at least one
19 incision made on the upper wall of the vagina;
20
21 inserting a first end of the surgical implant
22 behind the first side of the urethra;
23
24 locating a first fixing zone into the tissues
25 of the retropubic space fascia without
26 penetrating the rectus sheath;
27
28 inserting a second end of the surgical implant
29 behind a second side of the urethra; and
30
31 locating a second fixing zone into the tissues
32 of the retropubic space above without.

1 penetrating the rectus sheath, such that the
2 supporting zone passes under the urethra.
3
4 33. A method of transmitting intra-abdominal
5 pressure to the urethra comprising the steps of
6
7 introducing an anchor strip into at least one
8 incision made on the upper wall of the vagina;
9
10 inserting a first portion of the anchor strip
11 behind the first side of the urethra;
12
13 locating a first portion including a fixing
14 zone into the tissues of the retropubic space
15 above the endopelvic fascia without penetrating
16 the rectus sheath;
17
18 locating a second portion of the anchor strip
19 alongside the urethra in the suburethral
20 pressure compartment below the endopelvic
21 fascia;
22
23 inserting a second anchor strip behind a second
24 side of the urethra;
25
26 locating a first portion including a fixing
27 zone of the second anchor strip into the
28 tissues of the retropubic space above the
29 endopelvic fascia without penetrating the
30 rectus sheath; and
31

1 locating a second portion of the second anchor
2 strip alongside the urethra in the suburethral
3 pressure compartment below the endopelvic
4 fascia.

5

6 34. A method as claimed in any of claims 32 or 33
7 which further comprises the step of moving the
8 retaining means from an inserting position to a
9 retaining position.

10

11 35. Use of a method as claimed in any of claims 32
12 to 34 in treating urinary incontinence or
13 uterovaginal prolapse.

14

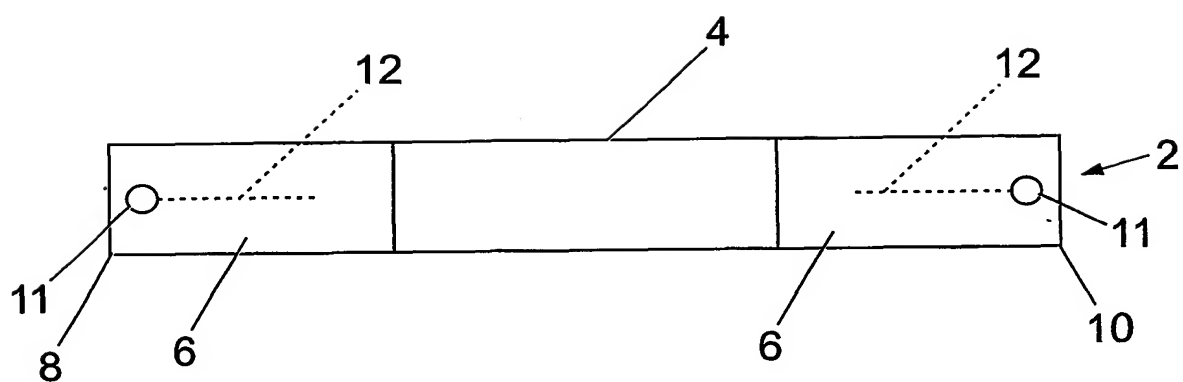
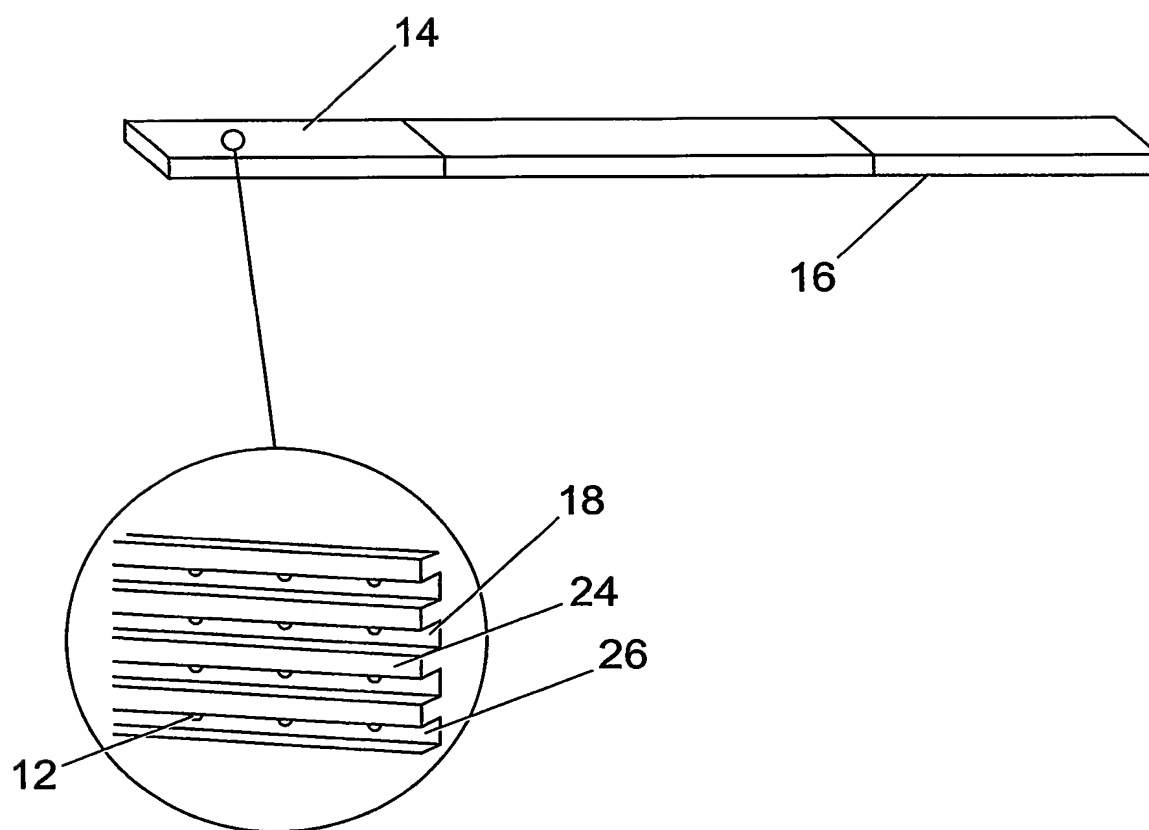


Fig. 1

*Fig. 2*

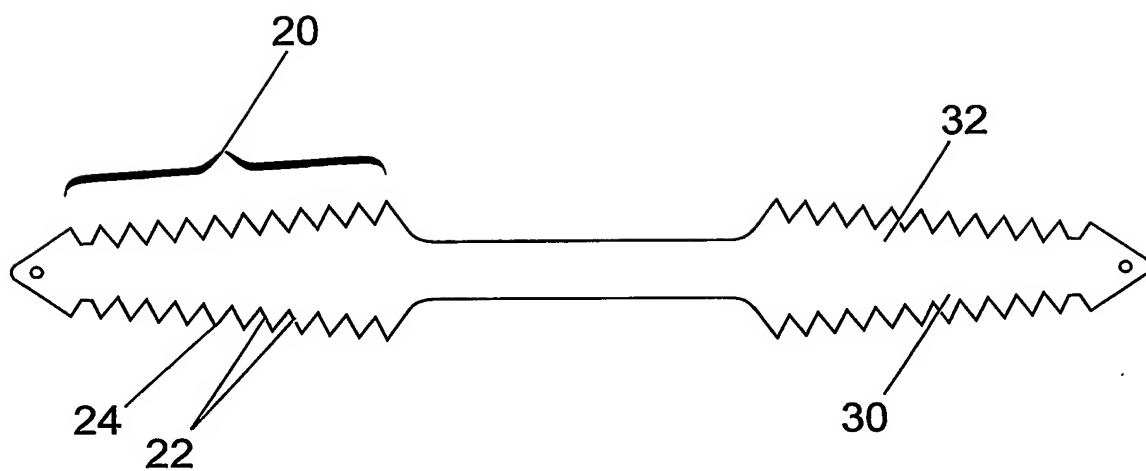
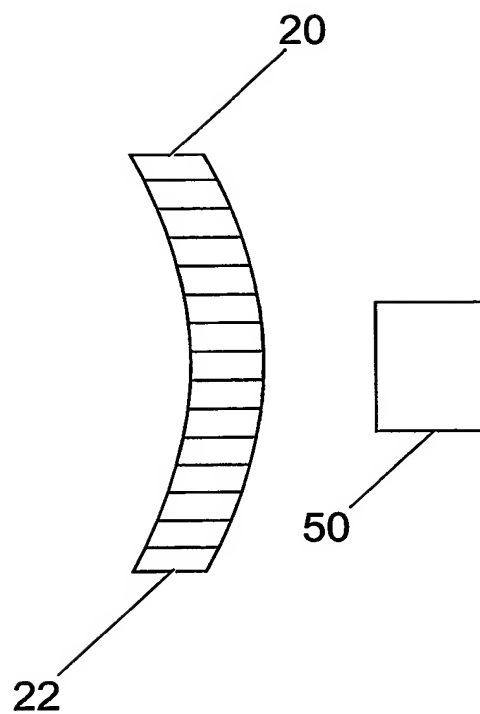
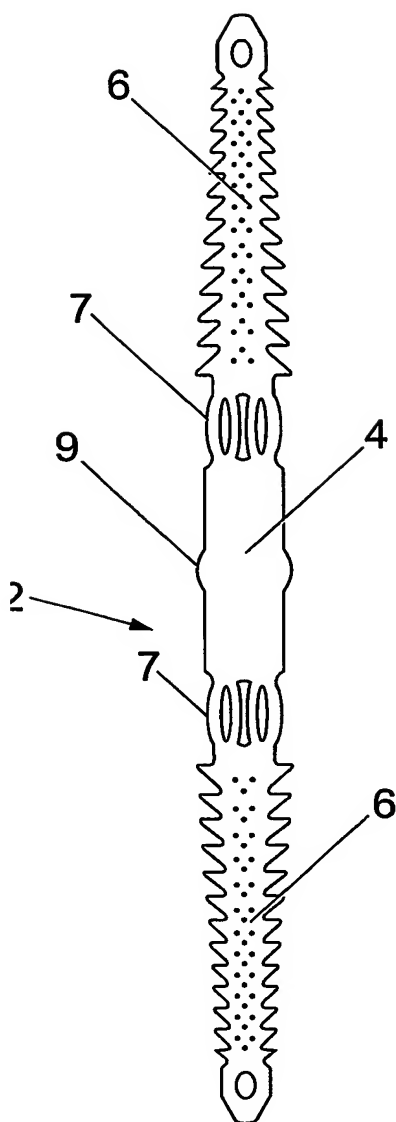


Fig. 3a

*Fig. 3b*

*Fig. 3c*

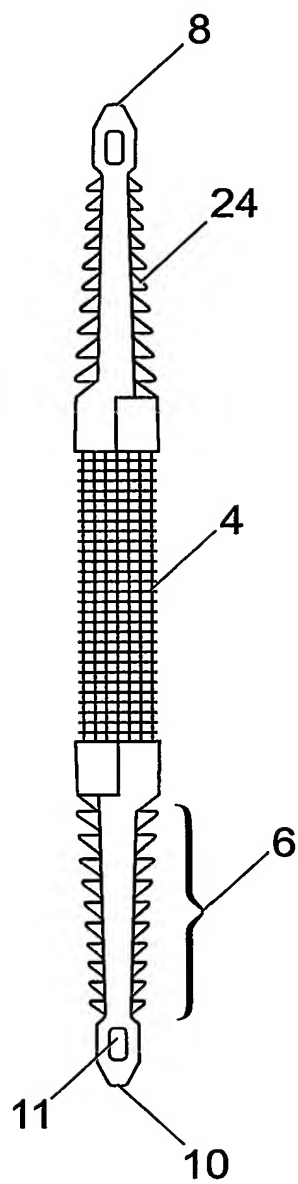


Fig. 4b

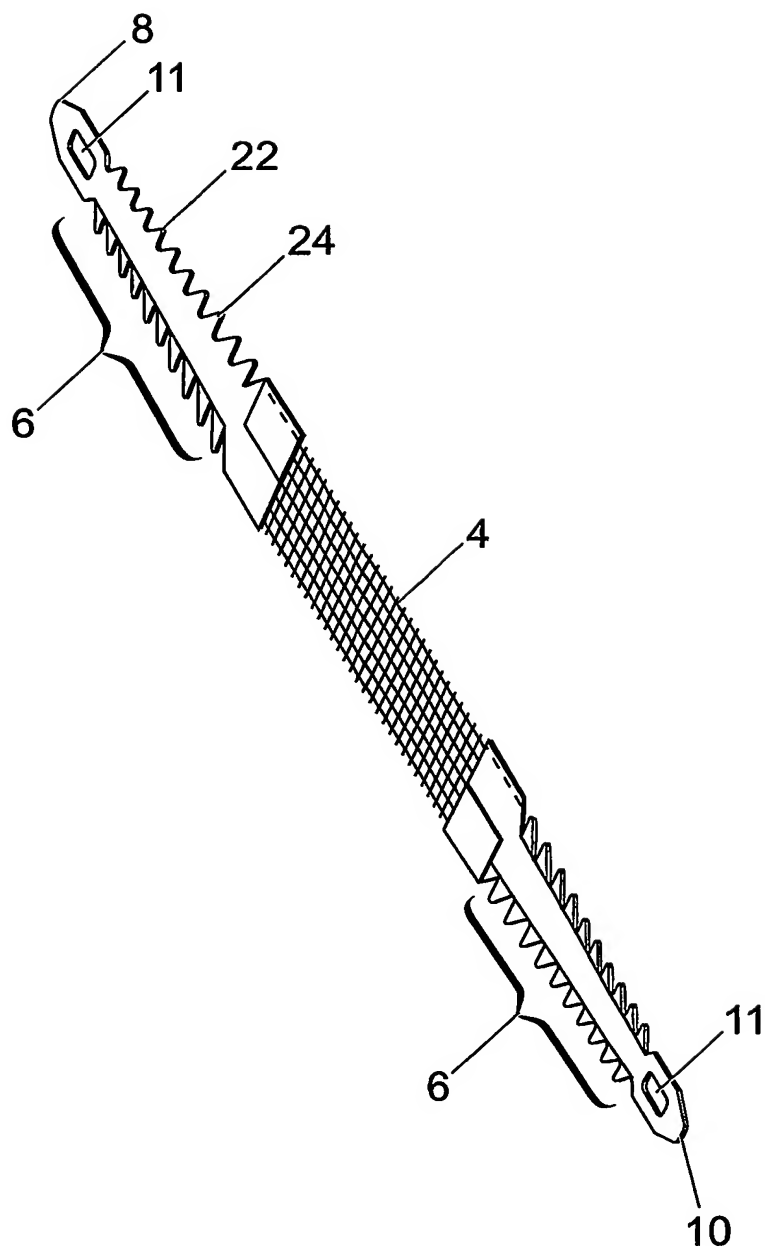
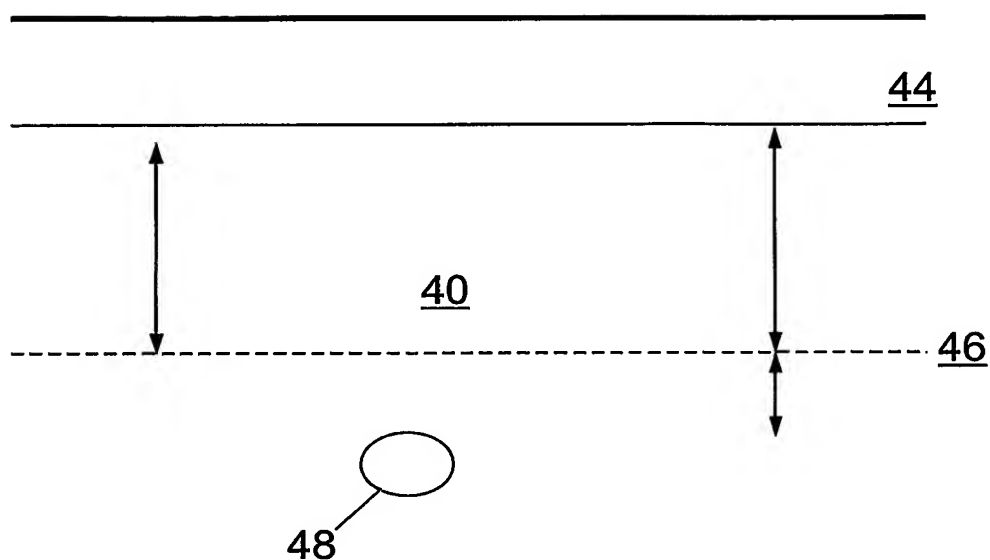


Fig. 4a

*Fig. 5*

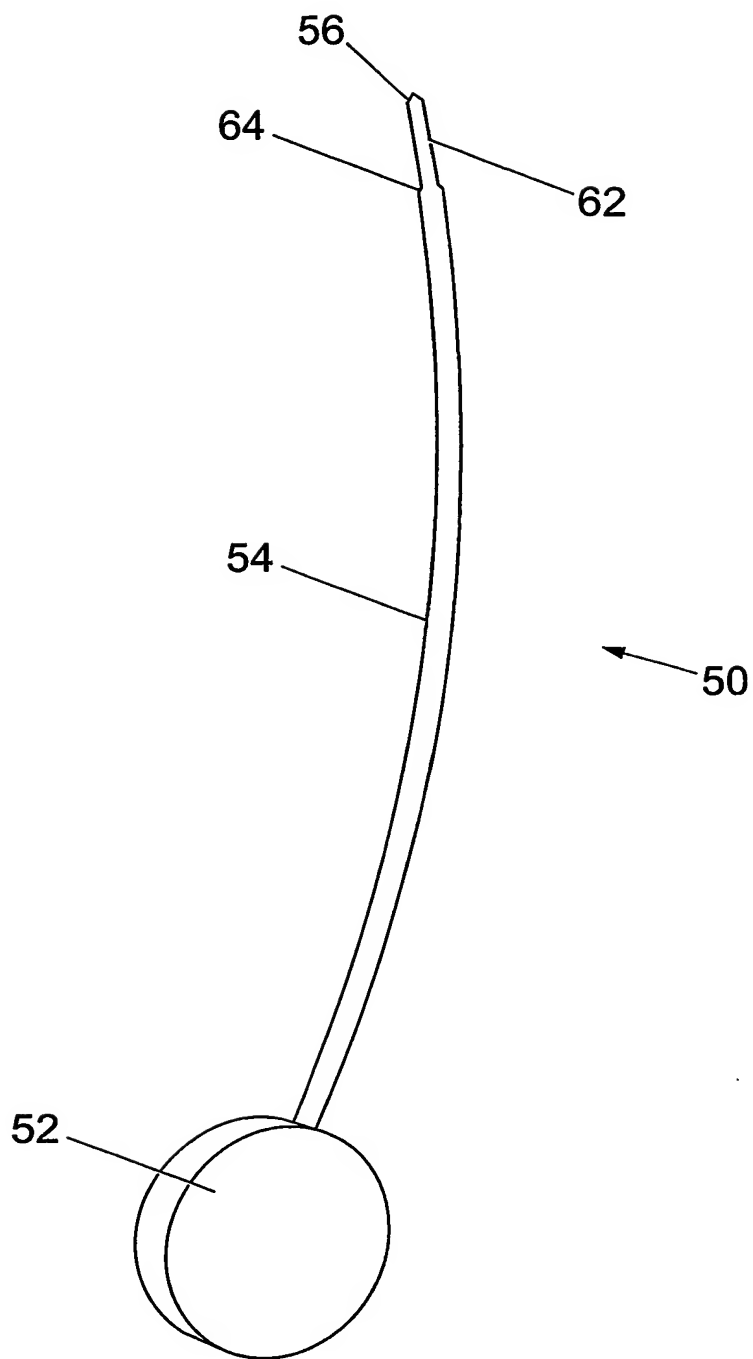


Fig. 6

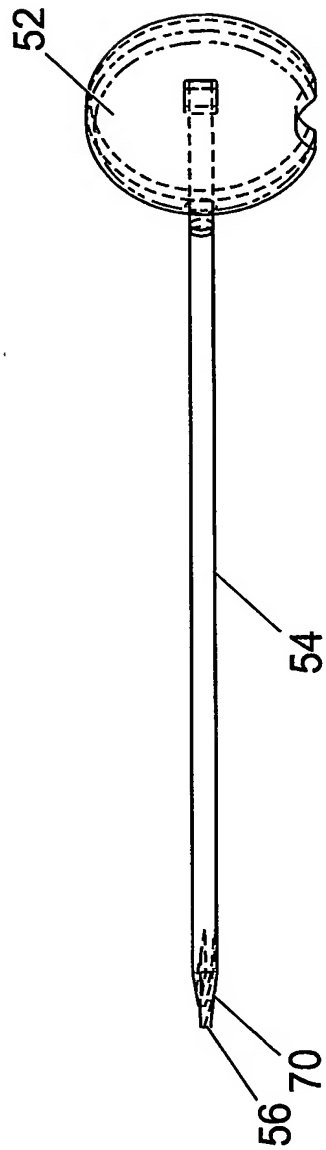


Fig. 7a

Fig. 7b

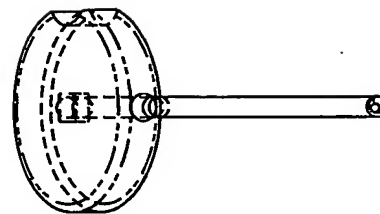


Fig. 7c

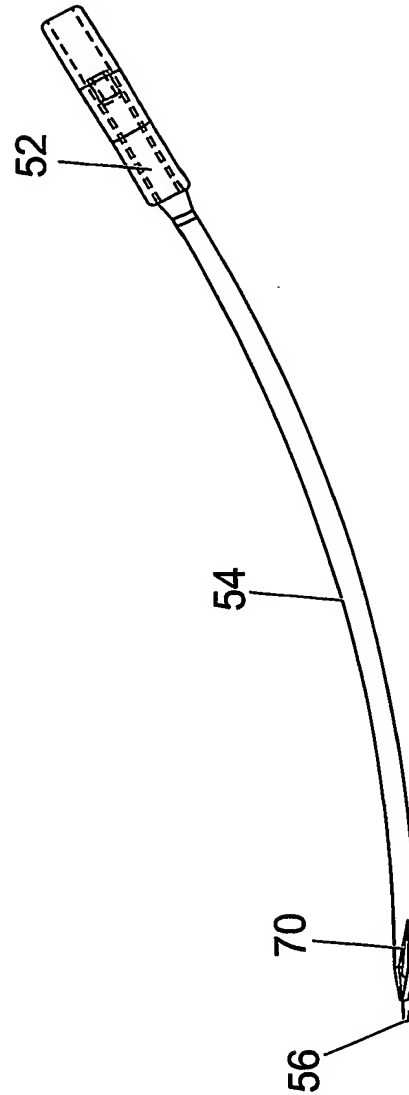
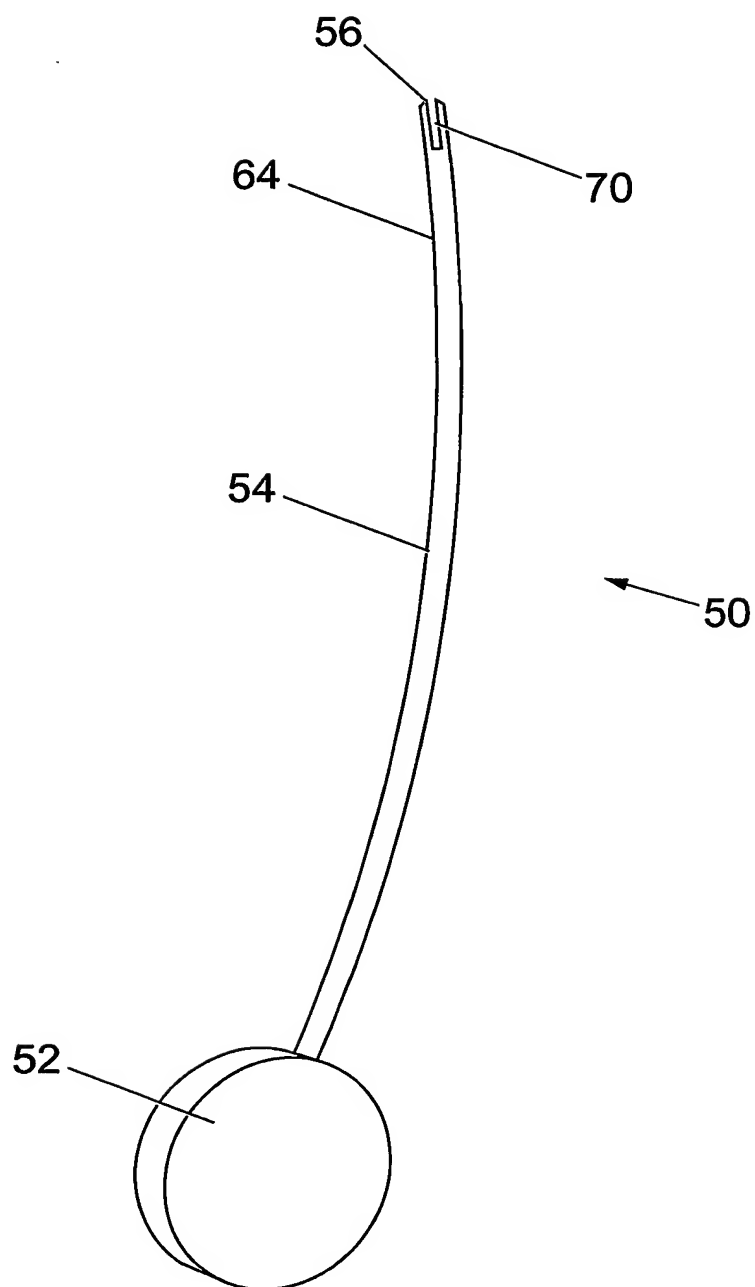


Fig. 7d

*Fig. 8*

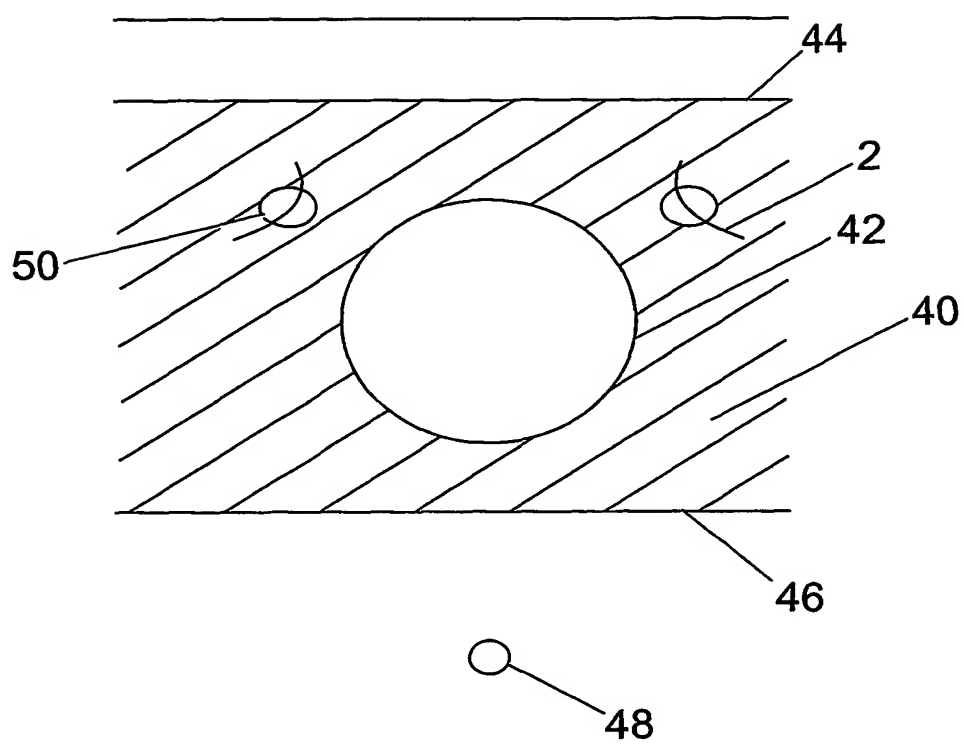
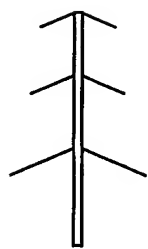
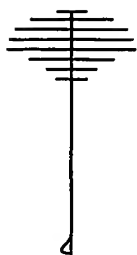


Fig. 9



(a)



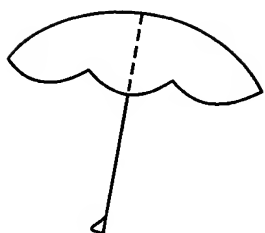
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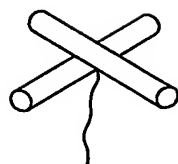
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(d)



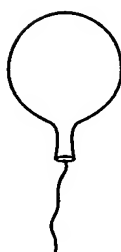
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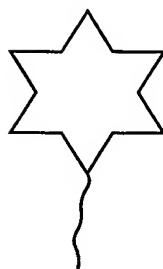
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(g)



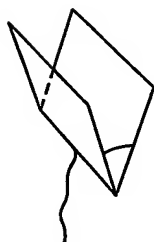
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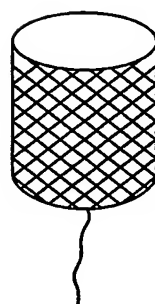
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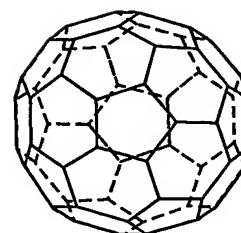
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(k)

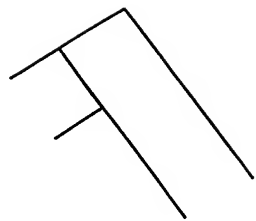


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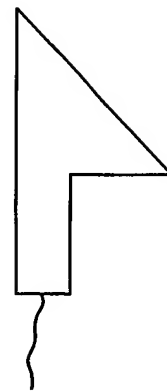


(m)

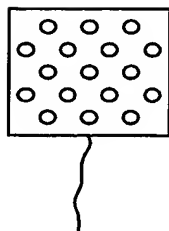
Fig. 10a



(n)



(o)

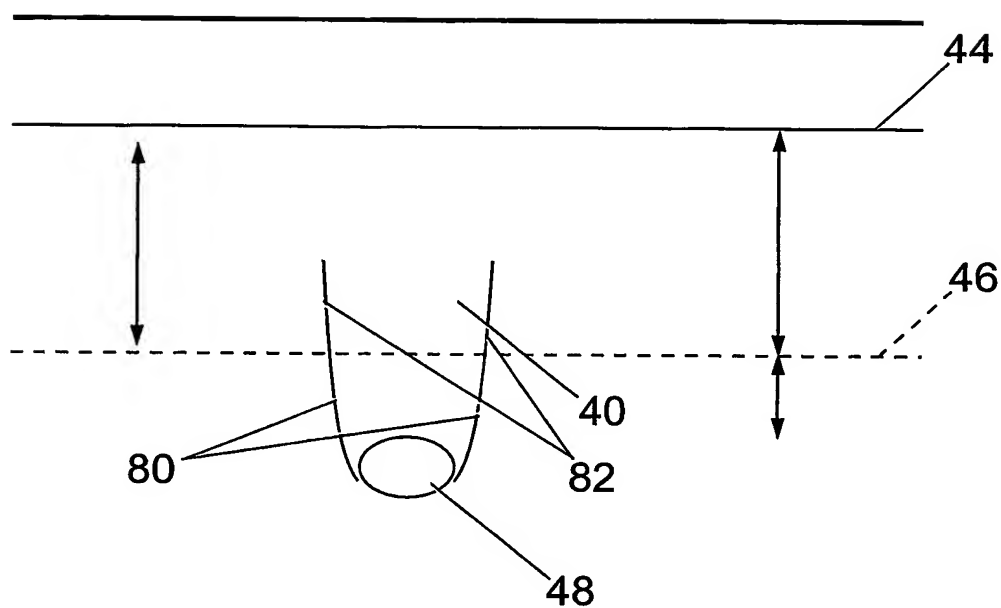


(p)



(q)

Fig. 10b

*Fig. 11*